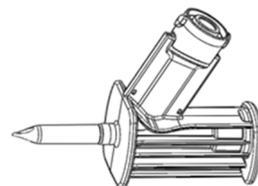




Closed Bag Adaptor

REF CBA100



Instructions for Use

Description

The Halo® Closed Bag Adaptor is a closed system spike adaptor intended for infusion preparation and administration of antineoplastic and hazardous drugs from vial to patient in a healthcare setting. Use required and accepted IV practice. Do not reuse to avoid contamination. Sterile (ethylene oxide). Sterile unless package is damaged. Rx Only.

Indication for Use

The Halo® system is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The Halo® system also prevents microbial ingress for up to 7 days.

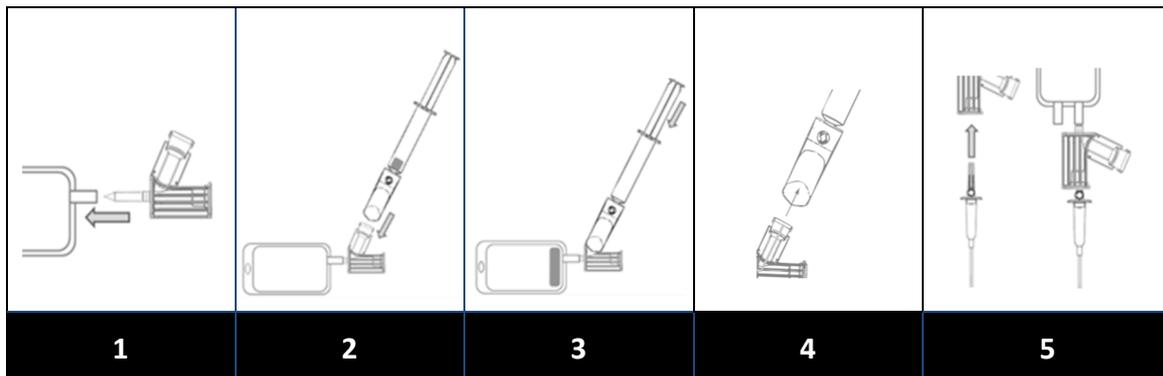
Precaution

Do not use if protective caps are loose or displaced. Not for fat emulsions or blood components. Always grip the white components when using the Corvida Medical Halo® System.

The sealing membranes are validated for up to 14 perforations. The performance of the sealing membrane may be reduced after multiple perforations. Discard after 14 perforations.

Warning

A non-vented IV set should be used with the Closed Bag Adaptor. If a vented IV set is used, make sure that the air inlet is closed throughout the infusion procedure.



Instructions

1. Remove protection cap from spike. Push piercing spike into the bag.
2. While holding the Closed Bag Adaptor port, connect the IV Set to the Closed Bag Adaptor, with the infusion container in horizontal position. Hold and Push the Closed Syringe Adaptor onto the connection interface of the Closed Bag Adaptor until fully seated.
3. Perform drug transfer.
4. Hold and pull the closed syringe adaptor to separate from the connection interface.
5. Spike the Closed Bag Adaptor with tubing administration set all the way into the Closed Bag Adaptors spike port.

Symbol Legend

- REF** Catalogue number
- LOT** Batch code
- Do not re-use
- Do not use if package is damaged
- Temperature limits to which the device can be safely exposed
- Caution, consult accompanying documents
- Sterilized using ethylene oxide
- Use by date
- Rx ONLY** Caution: Federal law (US) restricts this device to sale by or on the order of a physician
- Manufacturer Corvida Medical, Inc.

- Consult instructions for use
- Non-pyrogenic fluid path
- Not made with natural rubber latex
- Does not contain the Phthalate DEHP

Distributed By

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